

EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

**IN RE: JOHNSON & JOHNSON TALCUM
POWDER PRODUCTS MARKETING, SALES
PRACTICES, AND PRODUCTS LIABILITY
LITIGATION**

TAMARA NEWSOME,

Plaintiff,

v.

JOHNSON & JOHNSON, et al.,

Defendants.


MDL NO. 16-2738 (FLW) (LHG)

Civil Action No.3:18-cv- 17586-FLW-LHG

EXPERT REPORT OF CHERYL C. SAENZ, M.D.

Case-specific opinions regarding Ms. Tamara Newsome

Date: May 28, 2024


Cheryl C. Saenz, M.D.

Diagnosis and Treatment of Ovarian Cancer

[REDACTED]

[REDACTED]

[REDACTED]

¹ NewsomeT-HCHMR-00151

Clinical Cancer Genetics

She also relates that when

Ms. Newsome never actually had a consultation

Had Ms.

Newsome seen a

, if any, of her has not been identified, this does not necessarily mean that her was sporadic (i.e., not attributable to an inherited predisposition). This is because of two important limitations of the test. First, not all inherited predisposition to Research has identified other genes that when mutated can increase one's risk of cancer. Second, a small percentage of mutations in genes tested by this panel may be missed by current technology. Additionally, to try to identify if there are somatic mutations in her that would be targets for treatment with checkpoint inhibitors, or maintenance therapy.

Past Medical History

² NewsomeT-MOHA-MDR-000017.

³ February 4, 2021 Deposition Transcript of Ravin Garg, MD, p. 115.

⁴ February 4, 2021 Deposition Transcript of Ravin Garg, MD, p. 55, lines 2-6.

⁵ February 17, 2021 Deposition Transcript of Albert Steren, MD, p. 55.

• [REDACTED]
i [REDACTED]

Past Surgical History

• [REDACTED]
i [REDACTED]

Obstetrical/Gynecologic History

• [REDACTED]
i [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Summary

I have performed a thorough review of Ms. Newsome's medical records, the depositions of Tamara Newsome, Daniel Francois, Jr., Tae'lor Francois, Ravin Garg, M.D., and Albert Steren, M.D., as well as the Plaintiff Profile Forms, expert reports of Drs. Godleski and Clarke-Pearson, and the depositions of Dr. Clarke-Pearson. I have also reviewed the expert report of Dr. Teri Longacre, defense expert in the field of gynecologic pathology.

Ms. Newsome was [REDACTED]
[REDACTED] in March 2015. With [REDACTED]
[REDACTED] Even though Ms. Newsome [REDACTED]
[REDACTED] there is still a possibility that Ms. Newsome [REDACTED]
[REDACTED] that science has yet to identify that contributed to her development of [REDACTED].

Ms. Newsome's two primary risk factors for [REDACTED] were her age and the [REDACTED] that was found by Dr. Steren [REDACTED]. The [REDACTED] described by Dr. Steren in his [REDACTED], are classic findings for [REDACTED]. The presence of [REDACTED], was confirmed by the [REDACTED] performed by Dr. Longacre. "The [REDACTED] (Figures 3 and 4) (slide A8) as well [REDACTED] (Figures 5-7) (slides A13 and A15)."⁶ Examination of Figure 5 from Dr. Longacre's report demonstrates just how close in proximity the [REDACTED] actually

⁶ February 11, 2022 Expert Report of Teri Longacre, MD, page 7.

is to the [REDACTED].⁷ Dr. Clarke-Pearson's statement that "[t]here is no evidence of [REDACTED],"⁸ is thus incorrect.

As stated in my general causation report, the presence of endometriosis increases a woman's risk of developing endometrioid ovarian cancer by two - to threefold. That OR equates to a 100-200% increase in the risk of developing endometrioid ovarian cancer. Saavalainen and colleagues (2018), reported that women with ovarian endometriosis had an OR of 4.72 (2.75,7.56) of developing specifically endometrioid ovarian cancer, and even when the endometriosis was limited to the peritoneum there was still a twofold increase in the risk of endometrioid histology.⁹ Based on the surgical findings at the time of her [REDACTED], as well as the microscopic identification of [REDACTED], Ms. Newsome most likely carried the diagnosis of [REDACTED]. Thereby, the presence of [REDACTED] increased Ms. Newsome's risk of developing [REDACTED] somewhere in the range of 100 - 372%. Although no distinct causal mechanism can be identified for Ms. Newsome's [REDACTED], as is the case with all individual patients who develop [REDACTED] was most likely a substantial contributing factor. Dr. Steren, Ms. Newsome's gynecologic oncologist concurs, stating that "in most instances, the cause of ovarian cancer can't really be elucidated if they don't have a genetic predisposition." "We don't really know what causes them."¹⁰

In his expert report Dr. Clarke-Pearson states that Ms. Newsome did not have any risk factors for the development of [REDACTED]. At his deposition, however, he changed his opinion and agreed that her [REDACTED] contributed to her developing the disease, based on [REDACTED] Olsen et al. (2013) identified an OR of 1.37 increased risk of developing ovarian cancer in women with a BMI between 30.0-34.0.¹² In his deposition, Dr. Clarke-Pearson characterizes an OR of 1.37 as only "a slightly increased risk of developing ovarian cancer."¹³ He treats similar ORs associated with talc exposure very differently. In his expert report he writes that the "case-control studies show a 30-40% increased risk of EOC associated with genital talcum powder use,"¹⁴ and he asserts that this OR has demonstrated that genital use of talc can cause epithelial ovarian cancer. It is unscientific (and reflective of a results-driven approach) to state when applied to obesity an OR of 1.37 only slightly increases a woman's risk of developing ovarian cancer, and yet when it is the OR associated with the genital application of talc that talc is causal in the development of the disease.

⁷ February 11, 2022 Expert Report of Teri Longacre, MD, page 16.

⁸ July 2, 2021 Expert Report of Daniel Clarke-Pearson, MD, page 17.

⁹ Saavalainen, L., et al. Risk of gynecologic cancer according to the type of endometriosis. *Obstetrics & Gynecology*. 2018; 131(6), 1095-1102.

¹⁰ February 17, 2021 Deposition Transcript of Albert Steren, MD, p. 29, lines 13-17.

¹¹ March 8, 2024 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 321, lines 3-12.

¹² Olsen C.M., Nagle, C.N., Whiteman, D.C., Ness R., Pearce C.L., Pike M., Rossing M.A., Terry K., Wu A., et al. (2013). Obesity and risk of ovarian cancer subtypes: evidence from the Ovarian Cancer Association Consortium. *Endocr Relat Cancer*, 20(2): 251-62.

¹³ March 8, 2024 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 320, lines 9-18.

¹⁴ November 15, 2023 Amended Rule 26 Expert Report of Daniel Clarke-Pearson, MD, page 11.

Additionally problematic is the fact that Dr. Clarke-Pearson cites to Dr. Godleski's report to support his contention that the perineal application of talc caused Ms. Newsome to develop [REDACTED]. Dr. Godleski reports that he found 31 particles, which he claims represent talc in Ms. Newsome's [REDACTED]. Of note, the [REDACTED], where Dr. Godleski claimed to find the vast majority of the talc particles, did not contain [REDACTED]. Additionally, there is no evidence of an inflammatory response in the areas were Dr. Godleski states that he found talc particles.

In his report, Dr. Clarke-Pearson states that he has performed a differential diagnosis and concluded that Ms. Newsome's [REDACTED] was caused by the perineal application of talc. It is interesting to note that in prior testimony in February 2019, Dr. Clarke-Pearson concurred that we can never really know what causes ovarian cancer in any individual woman, stating:

A. What I think I understand your question being, if we can't identify a gene mutation, then we don't know what caused it. Is that what you're asking me?

Q. Yes.

A. Then the answer would be, yes, we don't know.¹⁵

Nonetheless, in deposition testimony in 2021, Dr. Clarke-Pearson stated that he can now determine the cause of an individual woman's ovarian cancer, retracting his prior testimony by stating, "Well, that was my answer at the time."¹⁶ Yet even in that deposition, he almost immediately retreated to his prior opinion, agreeing that "there is no way to tell, in an individual woman who used talc, whether she got ovarian cancer because of her talc use" or would have developed it anyway.¹⁷

Dr. Clarke-Pearson also misapplied the epidemiological concept of an odds ratio to reach a conclusion on specific causation. In 2024, when initially asked if he attributed 30 percent of Ms. Newsome's [REDACTED] to her talc use, he replied "Yes."¹⁸ Then, midway through this same deposition, he changed his opinion again and testified that 42% of Ms. Newsome's [REDACTED] was attributable to her talc use (based on a table in the Penninkilampi meta-analysis).¹⁹ This is a misapplication of epidemiological principles. A relative risk, even if it is affected by bias or other limitations, is not directly translatable to an individual's attributable risk of a cancer diagnosis.

¹⁵ February 4, 2019 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 94, lines 4-11.

¹⁶ August 26, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 215, line 2.

¹⁷ August 26, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 248 line 7-p. 249, line 2.

¹⁸ March 8, 2024 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 306, lines 15-19.

¹⁹ Penninkilampi, R., & Eslick, G. D. (2018). Perineal Talc Use and Ovarian Cancer. *Epidemiology*, 29(1), 41-49.

Conclusion

While Ms. Newsome states that she used baby powder daily from 1975-2015 for hygiene purposes, there is no credible scientific data to support the conclusion that the talc contributed to her development of [REDACTED]. The peer-reviewed scientific literature, nationally recognized and respected healthcare organizations (NCI, CDC, ACS, FDA), and the professional societies (SGO, ACOG) to which I belong, all maintain the position that talc does not cause ovarian cancer. All of the opinions herein are to a reasonable degree of medical probability. In addition, all of the general causation opinions contained in my General Expert Report dated May 21, 2024 are also incorporated herein.

MATERIALS RELIED ON AND CONSIDERED BY DR. CHERYL SAENZ

PLAINTIFF PROFILE FORM

1. 07/08/2020 Plaintiff Profile Form of Tamara Newsome

EXPERT REPORTS

1. 06/24/2021 Expert Report of John Godleski, MD
2. 07/02/2021 Expert Report of Daniel Clarke-Pearson, MD
3. 02/11/2022 Expert Report of Teri Longacre, MD
4. 11/15/2023 Amended Rule 26 Expert Report of Daniel Clarke-Pearson, MD

DEPOSITION TRANSCRIPTS

1. 02/04/2019 Deposition Transcript of Daniel Clarke-Pearson, MD
2. 12/09/2020 Deposition Transcript of Tamara Newsome
3. 02/04/2021 Deposition Transcript of Ravin Garg, MD
4. 02/17/2021 Deposition Transcript of Albert Steren, MD
5. 05/13/2021 Deposition Transcript of Daniel Francois, Jr.
6. 05/14/2021 Deposition Transcript of Tael'lor Amelia Francois
7. 08/26/2021 Deposition Transcript of Daniel Clarke-Pearson, MD (Vol. 1)
8. 08/27/2021 Deposition Transcript of Daniel Clarke-Pearson, MD (Vol. 2)
9. 01/17/2024 Deposition Transcript of Daniel Clarke-Pearson, MD
10. 03/08/2024 Deposition Transcript of Daniel Clarke-Pearson, MD

MEDICAL RECORDS

1. AAMC Oncology and Hematology (NewsomeT-AAMCOH-00007-00327)
2. Annapolis Oncology Center (NewsomeT-AOCMR-00001-00280)
3. Anne Arundel Medical Center (NewsomeT-AAMC-00001-00008; NewsomeT-AAMCMR-00006-00493; NewsomeT-AAMCRad-00019-00022)
4. Capital Women's Care (NewsomeT-CWCMR-00001-00103)
5. Community Radiology Associates (NewsomeT-CRAMR-00001-00011)
6. Holy Cross Hospital (NewsomeT-HCHMR-00001-00405; NewsomeT-HCHPath-00008-00113; NewsomeT-HolyCrossHospPath-00001-00007; NewsomeT-HCHRad-00001-00014)
7. Muttah, Sureshkumar, MD (NewsomeT-SMMLMR-00001-00027)
8. Myraid Genetics (NewsomeT-MGIMR-00001-00018)
9. Plaintiff Produced Medical Records (NEWSOMET_AAMC_C_MDR000001-410; NEWSOMET_C_CAPI_MDR000001-100; NEWSOMET_CAPI_MDR000001-23; NEWSOMET_GARG_C_MDR000001-101; NEWSOMET_GARG_MDR000001-76;

NEWSOMET_HCH_MDR000001-43; NEWSOMET_MOHA_MDR000001-2;
NEWSOMET_MUTTATH_C_MDR000001-81; NEWSOMET_MUTTATH_MDR000001-80;
NEWSOMET_PWHS_MDR000001-3; NewsomeT-MOHA-MDR-000003-000029;
NEWSOMET-REC00001-10; NewsomeT-WHSMR-00001-00020; NewsomeT-PPR-00085-00296)

10. Quest Diagnostics (NewsomeT-QDNISJC-00001-00058)
11. Supervalu Pharmacy (NewsomeT-SFP-00001-00023; NewsomeT-SPCO-00001-00023)
12. Target Compliance (NewsomeT-TPCO-00001-00006)
13. Washington Adventist Hospital (NewsomeT-WAHMR-00001-00075; NewsomeT-WAHMRPharm-00006-00020; NewsomeT-WAHRad-00001-00004)
14. White Oak Medical Center (NewsomeT-WOMCMR-00006-00088; NewsomeT-WOMCRad-00002-00007)
15. Women's Health Specialists of Montgomery County (NewsomeT-WHSMCLMR-00001-00019; NewsomeT-WHSMCLMR-00025-00098)

LITERATURE

1. Olsen C.M., Nagle, C.N., Whiteman, D.C., Ness R., Pearce C.L., Pike M., Rossing M.A., Terry K., Wu A., et al. (2013). Obesity and risk of ovarian cancer subtypes: evidence from the Ovarian Cancer Association Consortium. *Endocr Relat Cancer*, 20(2): 251-62.
2. Penninkilampi, R., & Eslick, G. D. (2018). Perineal Talc Use and Ovarian Cancer. *Epidemiology*, 29(1): 41-49.
3. Saavalainen, L., Lassus H., But A., Tiitinen A., Harkki P., Gissler M., Pukkala E., Heikinheimo O. (2018). Risk of gynecologic cancer according to the type of endometriosis. *Obstetrics & Gynecology*. 131(6): 1095-1102.

ADDITIONAL MATERIALS

1. Saed Confidential Documents (SAED_SEPT222021_SUPPL_000001-399)